

### **REMARKS**

Claims 1, 4, 6, 8-9, 11-17, 48 and 51-53 remain in the present application. Claims 2-3, 5, 7, 10, 18-47, and 49-50 are cancelled.

Claims 1, 4, 6, 8-9, 11-12 and 16-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Song, PCT Published Application No. WO 2005/016399 A1 (“Song”) in view of Talalay, U.S. Patent No. 4,063,367 (“Talalay”).

Claims 9, 13, 48 and 52-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and further in view of Kohnert et al., PCT Published Application No. WO 2003/043673 (“Kohnert”).

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and further in view of Lee et al., U.S. Patent No. 5,571,523 (“Lee”).

Claim 51 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and further in view of Gao et al., U.S. Patent No. 6,113,993 (“Gao”).

Claim 1 has now been amended. No new matter has been added. Reconsideration of the application in view of the amendment and following remarks is respectfully requested.

#### **Rejection of Claims 1, 4, 6, 8-9, 11-12 and 16-17 under 35 U.S.C. § 103(a)**

Claims 1, 4, 6, 8-9, 11-12 and 16-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Song, PCT Published Application No. WO 2005/016399 A1 (“Song”) in view of Talalay, U.S. Patent No. 4,063,367 (“Talalay”).

Song describes a method of making a medical device comprising (a) providing a solution comprising (i) solvent, (ii) a therapeutic agent, and (iii) an antioxidant; (b) providing a medical

device substrate; (c) contacting the solution with the medical device substrate; and (d) removing the solvent from the solution to form the therapeutic-agent-containing region. The therapeutic-agent-containing region can be formed, for example, by dipping the medical device substrate into the solution followed by drying to remove the solvent. Drying thereby occurs in a preheated oven. See Song, page 2, paragraph [0012], page 11, paragraph [0042], page 12, paragraph [0045] and page 13, paragraph [0051].

Talalay describes a method for rapidly drying liquid-solid composites and biologically active material in situ in a container. Containers are filled with a solution and placed on a conveyor which moves through a pre-drying housing or tunnel where ambient or gently warmed air is blown over the surface of the solution in the containers. The containers are then introduced into a chamber having a high vacuum on the order of about 500 microns in the chamber to complete the drying operation. A dry, positively sealed container of biologically active material which is not friable and which is well adhered to the wall of the container in which it is dried is thereby provided. See Talalay, column 1, lines 48-50, 57-59, column 2, lines 2-4, column 3, lines 22-25, column 4, lines 55-60 and column 6, lines 45-48.

Independent claim 1 has now been amended so as to recite a method of coating of a device with a substance comprising the steps of “providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” and “inserting the device into the solution of the coating substance within the receptacle of the container.” Support for the amendment can be found throughout the Specification as filed, for example, on page 23, line 30 to page 24, line 27. This section makes clear that the container can be a packaging container (“Thus, the container according to the present invention fulfills both functions, vessel for an in-situ coating process of the device (e.g. implant) and primary packaging system for long-term storage”). The container/packaging container furthermore comprises “a receptacle for receiving the device to be coated.” “[T]he receptacle of the container is furthermore coaxially located within a container housing” with the container comprising “an opening for passing the device and the coating solution/substrate or substance through to the receptacle ...”. No new matter was added.

Applicants respectfully submit that neither Song or Talalay teach or suggest “providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” or “inserting the device into the solution of the coating substance within the receptacle of the container” as is now recited in independent claim 1. Song teaches a method of making a medical device by dipping it into a solution followed by drying to remove the solvent. See Song, page 11, paragraph [0042] and page 12, paragraph [0045]. Song nowhere describes a container having a receptacle for receiving the device to be coated nor does Song describe that the receptacle of the container is coaxially located within a container housing. Song also nowhere describes providing a solution of the coating substance within the receptacle. Nor does Song describe inserting the device into the solution of the coating substance within the receptacle of the container. In fact, Song nowhere specifically describes either a container or a container having a receptacle. Talalay does not cure this defect. While Talalay describes containers containing a solution, Talalay nowhere describes a container having a receptacle for receiving a device to be coated nor does Talalay describe that the receptacle of the container is coaxially located within a container housing. In Talalay, the device that is coated is the container itself; “[t]he invention provides dry, positively sealed containers of biologically active material which is not friable and well adhered to the wall of the container in which it is dried.” See Talalay, column 6, lines 45-48. Talalay also nowhere describes providing a solution of the coating substance within the receptacle. Nor does Talalay describe inserting the device into the solution of the coating substance within the receptacle of the container as is now required by independent claim 1.

Because each of Song and Talalay are missing at least the recited elements of “providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” and “inserting the device into the solution of the coating substance within the receptacle of the container,” as now recited in claim 1, it is respectfully submitted that any combination of Song and Talalay, to the extent proper, could not render claim 1, or any of its dependent claims, obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection to claims 1, 4, 6, 8-9, 11-12 and 16-17 under 35 U.S.C. § 103(a) based on Song in view of Talalay is respectfully requested.

**Rejection of Claims 9, 13, 48 and 52-53 under 35 U.S.C. § 103(a)**

Claims 9, 13, 48 and 52-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and further in view of Kohnert et al., PCT Published Application No. WO 2003/043673 (“Kohnert”).

Song and Talalay were described above.

Kohnert describes a device having osteoinductive and osteoconductive properties in vivo comprising a carrier containing calcium phosphate and an osteoinductive protein. The device is prepared by providing a solution comprising an osteoinductive protein and a buffer and contacting the solution with a carrier containing calcium phosphate. See Kohnert, page 6, line 27 to page 7, line 4 and the Abstract.

It is respectfully submitted that each of claims 9, 13, 48 and 52-53 properly depend from independent claim 1. As stated above, each of Song and Talalay fail to teach or suggest “providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” or “inserting the device into the solution of the coating substance within the receptacle of the container” as is now recited in independent claim 1. Kohnert does not cure this defect. Kohnert nowhere describes a container having a receptacle for receiving the device to be coated nor does Kohnert describe that the receptacle of the container is coaxially located within a container housing. Kohnert also nowhere describes providing a solution of the coating substance within the receptacle. Nor does Kohnert describe inserting the device into the solution of the coating substance within the receptacle of the container as is now required by independent claim 1.

Because each of Song, Talalay and Kohnert are missing at least the recited elements of “providing a container having a receptacle for receiving the device to be coated, wherein the

receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” and “inserting the device into the solution of the coating substance within the receptacle of the container,” as recited in claim 1, it is respectfully submitted that any combination of Song, Talalay and Kohnert, to the extent proper, could not render claim 1, or any of its dependent claims 9, 13, 48 and 52-53, obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection to claims 9, 13, 48 and 52-53 under 35 U.S.C. § 103(a) based on Song in view of Talalay and further in view of Kohnert is respectfully requested.

**Rejection of Claim 15 under 35 U.S.C. § 103(a)**

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and further in view of Lee et al., U.S. Patent No. 5,571,523 (“Lee”).

Song and Talalay were described above.

Lee describes a method of inhibiting arteriosclerosis or smooth muscle cell proliferation by identifying an animal having an artery suspected of needing inhibition and contacting the artery with an apoptosis-inducing amount of an antioxidant such as methionine. See Lee, column 1, lines 37-40 and the Abstract.

It is respectfully submitted that claim 15 properly depends from independent claim 1. As stated above, each of Song and Talalay fail to teach or suggest “providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” or “inserting the device into the solution of the coating substance within the receptacle of the container” as is now recited in independent claim 1. Lee does not cure this defect. Lee nowhere describes a container having a receptacle for receiving the device to be coated nor does Lee describe that the receptacle of the container is coaxially located within a container housing. Lee also nowhere describes providing a solution of the coating substance within the receptacle. Nor does Lee describe inserting the device into the solution of the coating substance within the receptacle of the container as is now required by independent claim 1.

Because each of Song, Talalay and Lee are missing at least the recited elements of “providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” and “inserting the device into the solution of the coating substance within the receptacle of the container,” as recited in claim 1, it is respectfully submitted that any combination of Song, Talalay and Lee, to the extent proper, could not render claim 1, or its dependent claim 15, obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection to claim 15 under 35 U.S.C. § 103(a) based on Song in view of Talalay and further in view of Lee is respectfully requested.

**Rejection of Claim 51 under 35 U.S.C. § 103(a)**

Claim 51 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and further in view of Gao et al., U.S. Patent No. 6,113,993 (“Gao”).

Song and Talalay were described above.

Gao teaches a method of coating a substrate with a calcium phosphate compound using plasma enhanced MOCVD. The substrate can thereby be a titanium alloy. See Gao, column 3, lines 4-8 and the Abstract.

It is respectfully submitted that claim 51 properly depends from independent claim 1. As stated above, each of Song and Talalay fail to teach or suggest “providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” or “inserting the device into the solution of the coating substance within the receptacle of the container” as is now recited in independent claim 1. Gao does not cure this defect. Gao nowhere describes a container having a receptacle for receiving the device to be coated nor does Gao describe that the receptacle of the container is coaxially located within a container housing. Gao also nowhere describes providing a solution of the coating substance within the receptacle.

Nor does Gao describe inserting the device into the solution of the coating substance within the receptacle of the container as is now required by independent claim 1.

Because each of Song, Talalay and Gao are missing at least the recited elements of “providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing,” “providing a solution of the coating substance within the receptacle” and “inserting the device into the solution of the coating substance within the receptacle of the container,” as recited in claim 1, it is respectfully submitted that any combination of Song, Talalay and Gao, to the extent proper, could not render claim 1, or its dependent claim 51, obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection to claim 51 under 35 U.S.C. § 103(a) based on Song in view of Talalay and further in view of Gao is respectfully requested.

**CONCLUSION**

Applicants believe that the only fees due for this submission are \$ 810.00 for the Request for Continued Examination and \$ 1,110.00 for a three month extension of time. The Commissioner is hereby authorized to charge said \$ 1,920.00 as well any unpaid fees deemed required in connection with this submission, including any additional filing or application processing fees required under 37 C.F.R. §1.16 or 1.17, or to credit any overpayment, to Deposit Account No. 50-5256.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Favorable action is earnestly solicited.

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Respectfully submitted,

By Norman B. Thot  
Norman B. Thot

Registration No.: 47,993  
PATENT LAW OFFICES OF  
DR. NORMAN B. THOT  
P.O. Box 10 17 56  
40837 Ratingen / Germany  
(+49 2102) 168928-0  
(+49 2102) 168928-20 (FAX)  
Attorney For Applicants